

(7) Comment No. LET36, Docket No. 80N-0042, Dockets Management Branch.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of a rule on small entities. This final rule stays the effective date of testing requirements that became effective on October 7, 1996, but which will not be required now until October 7, 1997. Thus, this final rule will not impose a significant economic burden on affected entities. Therefore, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Commissioner of Food and Drugs certifies that this final rule will not have a significant economic impact on a substantial number of small entities. No further analysis is required.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 355

Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 355 is amended as follows:

PART 355—ANTICARIES DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 355 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

§ 355.70 [Partial stay]

2. In § 355.70 *Testing procedures for fluoride dentifrice drug products*, paragraph (a) is stayed until October 7, 1997.

Dated: December 5, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96-31575 Filed 12-13-96; 8:45 am]

BILLING CODE 4160-01-F

AGENCY FOR INTERNATIONAL DEVELOPMENT

22 CFR Part 210

Donation of Dairy Products To Assist Needy Persons Overseas (Section 416 Foreign Donation Program)

AGENCY: Agency for International Development, IDCA.

ACTION: Final rule.

SUMMARY: The authority for donations of dairy products to assist the needy overseas has been removed from the Agency for International Development, thereby making these regulations obsolete. These donation regulations are being removed.

EFFECTIVE DATE: December 16, 1996.

FOR FURTHER INFORMATION CONTACT: James Dempsey, Director, Office of Planning and Program Evaluation (AID/BHR/PPE), Bureau for Humanitarian Response, USAID, (703) 351-0102.

SUPPLEMENTARY INFORMATION: 22 CFR part 210 is obsolete. New regulations are being issued by the U.S. Department of Agriculture. The 22 CFR, part 210 rule is not a major rule for purposes of Executive Order 12291 of February 17, 1991. As required by the Regulatory Flexibility Act, it is hereby certified that this rule will not have a significant impact on small business entities.

List of Subjects in 22 CFR Part 210

Agricultural commodities, Foreign assistance.

PART 210—[REMOVED]

For the reasons set forth above, 22 CFR part 210 is removed.

Authority: 22 U.S.C. 2381(a).

Dated: November 22, 1996.

James Dempsey,

Director, AID/BHR/PPE.

[FR Doc. 96-30990 Filed 12-13-96; 8:45 am]

BILLING CODE 6116-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 8690]

RIN-1545-AS94

Deductibility, Substantiation, and Disclosure of Certain Charitable Contributions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance regarding the allowance of certain charitable contribution deductions, the substantiation requirements for charitable contributions of \$250 or more, and the disclosure requirements for quid pro quo contributions in excess of \$75. The regulations will affect organizations described in section 170(c) and individuals and entities that make payments to these organizations.

EFFECTIVE DATE: These regulations are effective December 16, 1996.

FOR FURTHER INFORMATION CONTACT: Jefferson K. Fox of the Office of Assistant Chief Counsel (Income Tax and Accounting) at 202-622-4930 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1545-1464. Responses to this collection of information are required for charitable contribution deductions under section 170.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number.

The estimated annual burden per recordkeeper varies from three minutes to one hour, depending on individual circumstances, with an estimated average of six minutes.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, PC:FP, Washington, DC 20224, and to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and